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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,575	07/21/2003	Nils-Gunnar Holmer	150-126	3373

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Steven S. Payne
8027 ILIFF Drive
Dunn Loring, VA 22027

EXAMINER

CHENG, JACQUELINE

ART UNIT	PAPER NUMBER
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3768

MAIL DATE	DELIVERY MODE
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09/21/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/622,575

Applicant(s)

HOLMER, NILS-GUNNAR

Examiner

Jacqueline Cheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15, 16 and 18-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15 16 18-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claim 15, 16, 18, 19, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio (US 5,471,988).
3. **Claims 15, 16, 29, and 30:** Fujio discloses an ultrasonic probe which is inserted into a body cavity for observation and therapy of a lesion. The probe comprises a transducer that is connected to an ultrasound generator to emit therapeutic ultrasonic energy and a balloon for holding a liquid which is detachable from the distal-end part of the ultrasonic probe (col. 9 line 10-27). This balloon can be filled with a cooling liquid for both as an acoustic medium as well as to protect from heat damage to living tissue. This cooling liquid is circulated through the balloon (fig. 53 element 250) by an outlet port (suction passage, fig. 53 element 255) and an inlet port (feeding passage, fig 53 element 248). The expandable balloon can be filled and expanded to a desired size, allowing for adjustment of the relative position of the transducer and the patient surface (col. 45 line 62-col. 46 line 42). Fujio also discloses an embodiment of the probe in which the cooling liquid is in contact with a surface of the transducer. In figure 64 the observation transducer and the therapeutic transducers are arranged over the circumference of the distal end of the probe (col. 53 line 29-43). It would be obvious to combine these embodiments

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of Fujio as Fujio discloses that his invention includes combinations of his many embodiments (col. 62 line 61-64).

4. Fujio does not explicitly disclose the balloon being exchangeable, but as the balloon is removably attached it would be obvious to one skilled in the art to use a different balloon covering in when it is attached again, in order to prevent contamination between patients.

5. **Claims 18, 19:** Fujio discloses an embodiment that includes a temperature sensor to measure the temperature of the water which is used to set the circulation control which controls the temperature of the circulating fluid (col. 46 line 43-col. 47 line 6).

6. **Claims 20 and 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio further in view of Ishibashi (US 5,984,881). Ishibashi discloses an ultrasound therapeutic apparatus that consists of a therapeutic ultrasonic wave generator and an imaging probe. The imaging probe is used to receive echoes of the ultrasonic pulses. The driving conditions for the therapeutic ultrasonic wave generating source is then adjusted on the basis of the received echo signal (abstract). The system is capable of forcibly stopping the therapy so the system is capable of adjusting the therapeutic waves to stop based on the echo signals of the tissue. It would be obvious to one with ordinary skill in the art at the time of the invention to combine Ishibashi with Fujio as it is important to know when to stop and start therapy depending on the conditions of the tissue.

7. **Claim 22** is rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio in view of Ishibashi as applied to claim 20 above, and further in view of MacCarter (US 6,858,006 B2).

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MacCarter discloses a system for monitoring health information of patients. This system includes an ultrasonic sensor that can emit sound waves from the skin's epidermal layer to a distal portion and then calculate the reflection transit time as a correlation to tissue thickness (col. 13 line 5-13). It would be obvious to combine MacCarter with Fujio and Ishibashi as the echoes of the ultrasonic wave are already collected it is just a matter of processing the information, the information of tissue thickness would be an obvious thing to need or want in order to know how deep to scan the ultrasonic waves.

8. Claims 15, 16, 18, 19, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fujio in view of Weng (US 6,626,855 B1).

9. **Claims 15, 16, 29 and 30:** Fujio discloses an ultrasonic probe which is inserted into a body cavity for observation and therapy of a lesion. The probe comprises a transducer that is connected to an ultrasound generator to emit therapeutic ultrasonic energy and a balloon for holding a liquid which is detachable from the distal-end part of the ultrasonic probe (col. 9 line 10-27). This balloon can be filled with a cooling liquid for both as an acoustic medium as well as to protect from heat damage to living tissue. This cooling liquid is circulated through the balloon (fig. 53 element 250) by an outlet port (suction passage, fig. 53 element 255) and an inlet port (feeding passing, fig 53 element 248) The expandable balloon can be filled and expanded to a desired size, allowing for adjustment of the relative position of the transducer and the patient surface. Cooling liquid is also circulated by the transducer surface in order to remove heat from the radiating surface of transducer. In the embodiment of Fujio the liquid circulating within the

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transducer surface and the liquid circulating within the balloon are separated by an acoustic window (col. 44 line 55-col. 46 line 42).

10. Weng discloses a same type of ultrasonic system comprising a observation and therapy transducers with a balloon circulating fluid to keep both the transducer and patient surface cool. It would be obvious to combine Weng with Fujio to remove the acoustic window in order to simplify Fujio to need only one inlet and outlet to circulate the fluid. It would also be obvious to combine Fujio with Weng to provide a removable bag in order to use the same transducer for multiple uses, as some embodiments in Weng do not use a balloon and some embodiments do.

11. Fujio does not explicitly disclose the balloon being exchangeable, but as the balloon is removably attached it would be obvious to one skilled in the art to use a different balloon covering in when it is attached again, in order to prevent contamination between patients.

12. **Claims 18, 19:** Fujio discloses an embodiment that includes a temperature sensor to measure the temperature of the water which is used to set the circulation control which controls the temperature of the circulating fluid (col. 46 line 43-col. 47 line 6).

13. **Claims 23-28** are rejected under 35 U.S.C. 102(a) as being anticipated by Fujio in view of Slayton (US 6,050,943). Fujio discloses most of what is claimed as disclosed above. What Fujio does not disclose is the particulars of how his ultrasonic observation and therapy is performed. It would be obvious to use any well known ultrasonic observation and therapy system well known in the art such as disclosed by Slayton. In Slayton ultrasonic waves (diagnostic energy) are directed into the body and generates an image, from the echo pulses returned, of the treatment region to assist the user in positioning the transducers to the treatment region. The

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ultrasonic therapy performs, through an acoustic transducer, therapeutic heating to the target tissue (abstract). The transducer is controlled by drivers that steer, and/or focus the waves to the region of interest in the target tissue. The heating power and time are also controlled to provide the proper heating pattern and therapeutic dosage (col. 7 line 45-54). The emitted acoustic waves of the therapeutic ultrasound can also be pulsed in the time domain, emitting energy in periods spaced by pauses (col. 5 line 64-col. 6 line 6).

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline Cheng whose telephone number is 571-272-5596. The examiner can normally be reached on M-F 10:00-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER

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